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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/748,739	12/26/2000	Oksana Lockridge	P-IX 4143	4261
25885	7590	01/19/2005	EXAMINER	
ELI LILLY AND COMPANY PATENT DIVISION P.O. BOX 6288 INDIANAPOLIS, IN 46206-6288			CELSA, BENNETT M	
			ART UNIT	PAPER NUMBER
			1639	

DATE MAILED: 01/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/748,739

Applicant(s)

LOCKRIDGE ET AL.

Examiner

Bennett Celsa

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/10/04 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Claims

Claims 1-2 are currently pending and under consideration.

Election/Restriction

Applicant's election with traverse of Group I (claims 1-2, in part, drawn to a peptide comprising substantially the same amino acid sequence as seq. Id 2) in Paper No. 10 is again acknowledged.

Withdrawn Objection (s) and/or Rejection (s)

Applicant's amendment has overcome:

- a. The rejection of claims 1 and 2 under 35 U.S.C. 112, first paragraph, for LACK OF WRITTEN DESCRIPTION.
- b. The indefinite rejection of claims 1 and 2 over the terms "butyrylcholinesterase variants" and "substantially the same amino acid sequence" .

The provisional double patenting rejection of claims 1 and 2 over claims 1-33 (especially claims 1-2) of copending Application No. 10/032,233 as shown by PG PUB US 2003/0153062 (Aug. 14, 2003) is withdrawn since this application was converted to a provisional application which was later abandoned.

Outstanding Objection (s) and/or Rejection (s)

Claim Rejections - 35 USC § 112

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In newly amended claims 1 and 2, "A butylcholine esterase variant ... 95% sequence identity to a sequence of amino acid residues 1 or about 29 through 602, inclusive ... as SEQ ID 2 ... has a trptophane at amino acid position 328" is indefinite since there is NOT a tryptophan residue at position 328 of SEQ. ID 2 as presently claimed.

Discussion

Applicant's amendment and argument directed to the above indefinite rejection, (which was modified in response to applicant's amendment) was considered but deemed nonpersuasive for the following reasons.

Applicant argues that Fig. 1 contains a "signal sequence" (e.g. numbered -28 (met) to -1 (Thr) which is renumbered starting as amino acid number 1 which renders the trp at position 328 of fig. 1 equivalent to position 356 of seq. Id. 2.

This argument is not persuasive since claim 1 is addressing the amino acids as presented and NUMBERED in seq. 2 NOT AS REPRESENTED IN FIG. 1.

Accordingly, applicant can overcome this rejection by amending "amino acid position 328" to --- amino acid position 356 of SEQ. ID. 2 ---.

Thus, the above indefinite rejection, as revised, is hereby maintained.

New Objection (s) and/or Rejection (s)

Claim Objections

3. Claim 1 is objected to because of the following informalities: "tryptophane" should be spelled --- tryptophan ---. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (NEW MATTER REJECTION).

In claim 1 (and dependent claim 2, as amended 11/10/04), the language "**about 29**" in the phrase "... 95% sequence identity to a sequence of amino acid residues 1 or about 29 through 602, inclusive ... as SEQ ID 2" constitutes new matter to the extent that "about 29" is broader than 29. Fig. 1 provides support for a signal sequence of 28 amino acids (e.g. -1 to -28) which numbering is merely changed in seq. Id 2 (e.g. -1 in fig. 1 is amino acid 1 in seq. Id 2). This number shift does not provides support for claiming 95% sequence identity from amino acid positions corresponding to "about 29 through 602" of

Art Unit: 1639

seq. Id. 2 as presently claimed. Later sequences delete these 28 amino acids. However, there is no support for fragments which delete more or less than the first 28 amino acids and/or direct or representative support for fragments corresponding to "about 29" as a reference sequence for sequence identity claim coverage as presently claimed. Nor has applicant indicated where such supports exists.

5. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. In claim 1 (and dependent claim 2) The term "**about 29** through 602" in claim 1 is a relative term which renders the claim indefinite. The term "**about 29**" is not defined by the claim and the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For example, is 25 within the scope of "about 29"? How about 23, 24, 26, 30, 32 etc.

b. In claim 2, the phrase "having a 15-fold increase in cocaine hydrolysis activity" is indefinite since it fails to indicate what is being compared to the butyrylcholinesterase variant.

Applicants can overcome this rejection by amending consistent with specification page 22, lines 20-28 to recite "compared to human butylcholinesterase".

Double Patenting

6. Claims 1 and 2 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 8 of copending Application No. 10/413,432 alone and further in view of the specification (e.g. page 10) as evidence of inherency.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent application claims 1 and 2 teach a butyrylcholinesterase variant polypeptide comprising seq. Id. No. 52 which possesses cocaine hydrolysis activity (e.g. see claim 8). Seq. Id. No. 52 has 100% seq. Id. to amino acids 29-602 of seq. Id. 2 and possesses a trp at position 328. This polypeptide would additionally anticipate a polypeptide which includes the additional 28 amino acid peptide leader sequence, especially in view of the use of the term "comprising" which would include sequence structure. Further, the patent claim peptides clearly encompass A328W butyrylcholinesterase variants within the scope of the presently claimed invention (e.g. at least 95% sequence identity) and would be expected to inherently possess the requisite 15-fold increase in cocaine hydrolysis activity. See present specification at page 10 (especially lines 11-15).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

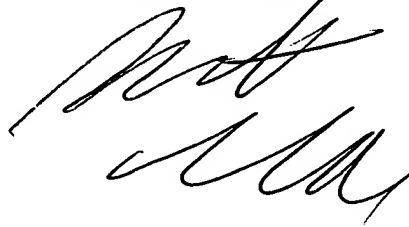
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 571-272-0807. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bennett Celsa
Primary Examiner
Art Unit 1639



BC
January 11, 2005